



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/076,115 05/12/98 GRUBER

C 0942.4350001

EXAMINER

HM12/1003

BRIAN J DEL BUONO
STERNE KESSLER GOLDSTEIN AND FOX
SUITE 600
1100 NEW YORK AVENUE NW
WASHINGTON DC 20005-3934

TUNG, J	
ART UNIT	PAPER NUMBER

1656
DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/076,115

Applicant(s)
Gruber et al

Examiner
Joyce Tung

Art Unit
1656



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/23/01
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 12, 16-20, 22, 25, and 28-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 12, 16-20, 22, 25, and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☒ Interview Summary (PTO-413) Paper No(s). 23
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 1656

DETAILED ACTION

In light of the following new ground of rejection, the finality of the Office action mailed 5/23/2001 is withdrawn.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29, and 31-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Burmer (5,726,022).

Burmer discloses that an adaptor with a restriction site is ligated to a first nucleic acid sample and optionally the adaptor may contain a ligand binding end. Further, Burmer discloses that if the first and second nucleic acid fragment are amplified, they are amplified with primers containing a ligand binding end and a sequence complementary to the adaptors (See column 2, lines 39-48). The teachings are inherent that the primer of Burmer contains all the limitation as recited in claims 1, 2, 12, 16-17, 25, 28, 29.

Burmer discloses that amplification may be done by PCR, LCR or TAS (see column 8, lines 47-52) (as recited in claims 12, 16,). This indicates that the polypeptides as listed in claim 6 are involved in the method of the invention, for example, reverse transcriptase and *Taq* DNA

Art Unit: 1656

polymerase. The isolation step is done by first removing the adaptors by restriction enzyme, capturing the nucleic acid containing the ligand and then the nucleic acid that were not captured is isolated (see column 2, lines 56-59) (as recited in claims 20 and 31-32). The ligand includes hapten (see column 7, line 4) (as recited in claims 18-19). The solid support is described in column 7, lines 37-48 (as recited in claims 22).

Thus, the teachings of Burmer anticipate the limitations of claims 1, 2, 6, 12, 16-20, 22, 25, 28, 29, and 31-32.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1656

4. Claims 1, 2, 6, 12, 16, 17-19, 25, 28-29 and 31. rejected under 35 U.S.C. 103(a) as being unpatentable over Frohman (PCR protocols, a guide to methods and applications, 1990, pg. 28-38) in view of Lohman et al. (5,631,147).

Frohman discloses that a method, Rapid Amplification of cDNA Ends, involves a adapter primer containing restriction sites (See pg. 30)

Frohman does not disclose that the adapter primer contains ligands as recited in claim 1.

However, Lohman et al. disclose thermophilic strand displacement amplification for amplifying nucleic acid target sequence in which an oligonucleotide primer is labeled, i.e. comprises one or more ligands (See column 11, lines 1-5). Note that the labels can be biotin, i.e. ligand capable of becoming a nucleic acid ligand-hapten complex (See column 12, lines 6). Many amplification protocols are employed, for example, 3SR (See column 14, lines 21-31). Secondary amplification products are generated (See column 11, lines 32-34). A different restriction endonuclease recognition site may also be substituted (See column 14, lines 42-46).

The teachings of Frohman and Lohman et al. suggest the limitations of claims 1, 2, 6, 12, 16, 17-19, 25, 28-29 and 31.

One of ordinary skill in the art would have been motivated to combine the teachings of Frohman and Lohman et al. to make instant invention with a reasonable expectation of success because in order to label the adapter primer of Frohman, the method of Lohman et al. involves using the primer attached to ligand and such that the movement of the amplification of the method

Art Unit: 1656

of Frohman is tracked. Thus it would have been prima facie obvious to carry out the method as claimed.

5. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

September 30, 2001

A handwritten signature in black ink, appearing to read "E. Campbell", with a stylized, cursive script.

EGGERTON A. CAMPBELL
PRIMARY EXAMINER